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Reply to Fitzmaurice et al.: The LIBERATE Trial

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Reply to: The LIBERATE trial: Options to Reduce the Risk of Post-Procedural Pneumothorax and Length of Stay

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We appreciate Fitzmaurice and colleagues' acknowledgement of the excellent design, execution and findings of the LIBERATE Study showing very meaningful benefits of Zephyr Valves in patients with severe emphysema¹. Successful occlusion and reduction of target lobar volume allows healthier tissue to expand/better function and these volume shifts can lead to pneumothorax in some patients. There are various ways to address this reality. Fitzmaurice et al. report their limited single center experience in placing prophylactic chest tubes in all 8 patients that they treated with Zephyr valves for advanced emphysema. Although 34.4% of the 128 patients treated with Zephyr Valves within LIBERATE developed a pneumothorax, not all patients required a chest tube; 17% of those that developed a pneumothorax did not require chest tube placement¹. Subjecting all patients who undergo Zephyr valve placement with chest tube placement may not be advisable since chest tube placement is not without morbidity and mortality. Chest tube placement has been reported to have early and late complication rates of 3% and 8%, respectively, that includes pleural and chest wall bleeding, infection, patient discomfort, perforation of major intrathoracic organs and unintentional intra-parenchymal lung placement². Additionally, in the COPD patient population, errant anterior mediastinal placement in the hyperinflated chest has been reported to cause contralateral pneumothorax³. We have identified and reported patients who are most likely to present with significant challenges should they experience a pneumothorax, specifically patients in whom the most diseased lobe is not treated, AND the non-treated contralateral lung destruction score is >60%¹. Consideration of placement of a chest tube prophylactically may be most appropriate in these "high-risk" patients in whom the benefit to risk is more attractive versus placing them in

every patient. Maximizing the benefit to risk profile for Zephyr Valve treatment begins with proper patient selection i.e. those with little to no collateral ventilation (determined with StratX[®] QCT and/or Chartis[®]) and physician assessment for post-procedure management ranging from prophylactic chest tube placement versus the need for closer observation and duration of hospital stay. Future work and investigation as illustrated by Fitzmaurice and colleagues has promise to improve the safety profile and patient benefit of this procedure.

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